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K070818
p1/3

MK3A

510(k) Summary

APR - 6 2007

Proprietary name:	MK3A
Trade name:	**medilogAR4, medilogAR12**
Common name:	Ambulatory ECG Monitor, Holter Recorder
Classification name:	Ambulatory ECG Monitor (21 CFR 870.2800, Product Code DSH)
510(k) submitter:	TOM Medical Entwicklungs GmbH Anzengrubergasse 8, A-8010 Graz, Austria Tel. + 43 (316) 261609-0 Fax. + 43 (316) 261609-10
Contact person:	Thomas Hasiba, General Manager Graz, Tel. + 43 (316) 261609-14
Manufacturer:	Huntleight Healthcare Cardiology Products Division 35 Portmanmoor Road, Cardiff, Wales CF24 5HN, UK
Predicate devices:	Medilog FD4 [510 (k) Number K970902] DXP1000 [510 (k) Number K993618] (marketed as Medilog FD5)

1 Concise description of the device

1.1 General

The recorder (type reference AR4 or AR12) is used to record a 3 channel ECG and to measure the time intervals between consecutive R peaks in the ECG. The system is designed for a measuring duration of more than 24h and is therefore worn by the patient throughout the whole day. The preparation for the recording (attaching electrodes, etc.) is undertaken by the technician or doctor. During the recording, the instrument is carried in a special protective pouch which can be attached to a belt. After inserting a memory card and batteries, the instrument can be switched on by pressing and holding the button on the top of the instrument. The recording is stopped by pressing and holding the same button on the top of the instrument or the recorder stops the recording automatically after a pre-set time. The instrument is not designed for emergency monitoring purposes (intensive medical monitor); the instrument is only designed to record the ECG and/or information derived from ECG. The recorder is not protected against the effects of defibrillation as outlined in EN60601-2-25.
As well as measuring the ECG and the beat to beat heart rate, the instrument also records other information: HF component of the ECG (quantifies muscle artefacts or disturbances), time point of the P-wave, time point of the T-wave, and time point of the pacemaker pulse.

In addition the MedilogAR12 records the ECG amplitude – Due to the heart's mechanical connection to the ribcage, breathing causes the electrical heart vector to turn and therefore changes the ECG amplitude. This reveals information about the breathing frequency and QPA (pulse /breathing quotient).

The data is stored digitally on a memory card. After removing the memory card, the data can be read by an appropriate card reader (e.g. PCMCIA slot and adapter).

The recorder is not designed for emergency monitoring purposes (intensive medical monitor). It is only designed for recording the ECG and/or heart rate.

The recorder is not protected against the effects of defibrillation as outlined in EN60601-2-25.

The recorder is not suitable for infants weighing less than 10 kg (22 lbs).

1.2 Technology

The MedilogAR4 and MedilogAR12 Digital Holter Recorders measure the voltage difference to derive the electrical ECG from body surface electrodes. A ground electrode is used to keep ground potential of the measured patient and of the recorder at the same level.
After amplification the analogue signal is digitised using conventional 16 bit A/D converter. A microprocessor gathers the so sampled data. The microprocessor processes the data before it stores them onto a removable flash memory card (CompactFlash technology). Processing includes:

- Pacemaker spike detection
- R- peak detection
- R-S amplitude measurement
- PT- wave detection
- Resample to storage sample rate
- Loss-less delta coding (Huffmann)

The data stored on the flash memory card is organised in one Windows FAT16 file.

1.3 Indications for use

The MedilogAR4 and MedilogAR12 Digital Holter Recorders are used to record a 3 channel ECG and to measure the time intervals between consecutive R peaks in the ECG. The system is designed for a measuring duration of more than 24h and is therefore worn by the patient throughout the whole day. The preparation for the recording (attaching electrodes, etc.) is undertaken by the technician or doctor. During the recording, the instrument is carried in a special protective pouch which can be attached to a belt.
The instrument is not designed for emergency monitoring purposes (intensive medical monitor); the instrument is only designed to record the ECG and/or information derived from ECG. The recorder is not protected against the effects of defibrillation as outlined in EN60601-2-25.

The instruments also record other information: HF component of the ECG, time point of the P-wave, time point of the T-wave, and time point of the pacemaker pulse.

In addition the MedilogAR12 records the ECG amplitude.

Such monitoring is most frequent used for the indications below:

- Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
- Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.
- Evaluation of patients for ST segment changes (no online ST measurement implemented in recorder)
- Evaluation of a patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery)
- Clinical and epidemiological research studies.
- Evaluation of patients with pacemakers
- Reporting of time and frequency domain heart rate variability (no online calculation implemented in recorder)
- Reporting of QT interval (no online QT interval measurement implemented in recorder)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 4 2007

Tom Medical Entwicklungs Gmbh
c/o Mr. Stefan Preiss
TUV America, Inc.
1175 Old Highway 8 NW, Suite 104
New Brighton, MN 55112

Re: K070818
Trade/Device Name: Medilog AR4, MedilogAR12
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II
Product Code: DSH
Dated: March 22, 2007
Received: March 26, 2007

Dear Mr. Preiss:

This letter corrects our substantially equivalent letter of April 6, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

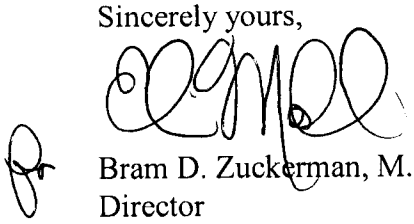
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other

requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

2 Device comparison table

The candidate devices Medilog AR4 and Medilog AR12, subject of this 510(k), have been compared to the following predicate devices: Medilog FD4 [510 (k) Number K970902], DXP1000 [510 (k) Number K993618] (marketed as Medilog FD5).

The significant differences to the Medilog FD4 are found as:

- **Infrared interface** – Medilog AR4 and Medilog AR12 recorders provide a infrared interface instead of a fibre optical cable. This improves the usability, as fibre optic interfaces to PCs became obsolete resently
- **Enhanced input voltage range** – more contemporary electronic provides better ECG quality for the sake of better ECG quality
- **Digital pacemaker detection** – The Medilog AR4 and Medilog AR12 are equipped with an internal spike detection algorithm offering a method for pacemaker functional analysis in Holter recordings
- **Digital R peak detection** – The R- peak detection feature is a preprocessing tool for off line beat detection algorithms to realign off line detected beats at a higher resolution, and, hence, provide a higher accuracy for e.g. HRV (heart rate variability) analysis.
- **R-S amplitude measurement** – The Medilog AR12 also records the R-S amplitude, which represents, according to several publications, an indicator for the heart position and movement in the chest, which is mainly induced by breathing and body position.

The significant differences to the Medilog FD5 (DXP 1000) are found as:

- **No display** – Instead of showing ECG traces directly on the recording device, the Medilog AR4 and Medilog AR12 recorders provide an infrared interface, compatible with PDAs and PCs. The ECG traces can then reviewed on a remote PDA or PC.
- **Enhanced input voltage range** – see discussion above
- **Digital R peak detection** – see discussion above
- **R-S amplitude measurement** – see discussion above

3 Summary for performance testing

Only bench tests were required to prove the device's performance.

The following tests have been performed:

Test	Benchmark	Criteria	Result
R peak detection	against MIT, AHA, and NST database	sensitivity and positive predictivity higher than 99% for MIT and AHA	PASSED
Pacemaker detection	Phantom artificial ECG signal generator	100% detection of pacemaker spikes in all programms	PASSED
PT wave detection	against QT database	sensitivity and positive predictivity higher than 80% for QT database	PASSED
RS amplitude measurement (EDR)	against a set of recordings with airflow channel	differences of mean deviation lower than 1 c/min	PASSED

4 Conclusion

The AR4/AR12 were found to meet all requirements. The devices are save and at least as effective, and perform at least as well as the predicate devices.

K070818

Indications for Use

510(k) Number (if known): not assigned yet

Device Name: MedilogAR4, MedilogAR12

Indications for Use:

The MedilogAR4 and MedilogAR12 Digital Holter Recorders are used to record a 3 channel ECG and to measure the time intervals between consecutive R peaks in the ECG. The system is designed for a measuring duration of more than 24h and is therefore worn by the patient throughout the whole day. The preparation for the recording (attaching electrodes, etc.) is undertaken by the technician or doctor. During the recording, the instrument is carried in a special protective pouch which can be attached to a belt.
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The instruments also record other information: HF component of the ECG, time point of the P-wave, time point of the T-wave, and time point of the pacemaker pulse.

In addition the MedilogAR12 records the ECG amplitude.

Such monitoring is most frequent used for the indications below:

1. Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
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3. Evaluation of patients for ST segment changes (no online ST measurement implemented in recorder)
4. Evaluation of a patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery)
5. Clinical and epidemiological research studies.
6. Evaluation of patients with pacemakers
7. Reporting of time and frequency domain heart rate variability (no online calculation implemented in recorder)
8. Reporting of QT interval (no online QT interval measurement implemented in recorder)

Prescription Use YES AND/OR ~~Over-The-Counter-Use~~ _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070818